

EPA REGISTRATION NUMBER 11556-155 VOL.1 – PART 2

ISB'S Front-end PRIA Completeness Screen

Draft 3; 10/25/07

EPA Receipt Date: 9/24		EPA Reg. Number: 11556-RLL		
	Check List Item	Yes	No	N/A
1	Has the PRIA Fee been Paid ; is a copy of the check or Pay.gov receipt included in the Submission Package?			
2	Is an Application Form (EPA Form 8570-1) Included in the Submission Package, is it completely filled out and signed including package type?	X		
3	Is a Confidential Statement of Formula (EPA Form 8570-29) Included in the Submission Package, is it completely filled out and signed (boxes 1-21)?	X		
4	Is a Formulator's Exemption Statement (EPA Form 8570-27) Included in the Submission Package?		X	
5	Is a Certification with Respect to Citation of Data (EPA Form 8570-34) Included in the Submission Package?	X		
6	Is a Data Matrix (EPA Form 8570-35) Included in the Submission Package?	X		
7	Is a Label Included in the Submission Package?	X		
8	Are Data Included in the Submission Package?	X		
9	Is the Submission an Amendment?			

Bayer HealthCare
Animal Health



Via Federal Express

February 14, 2013

Document Processing Desk (AMEND - NO REGFEE)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Attention: Mr. Richard Gebken/PM10
Registration Division (7505P)

Subject: Flumethrin Technical (EPA Reg. No. 11556-154)
PNR1427 Insecticide (EPA Reg. No. 11556-155); ABN: Seresto
Amendments to remove time-limited registration designations

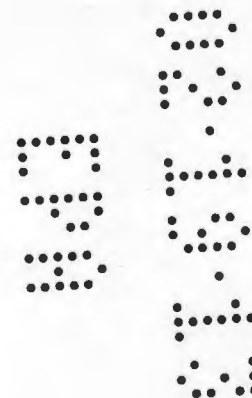
Bayer HealthCare LLC
Animal Health
P.O. Box 390
Shawnee Mission, KS 66201-0390

Dear Mr. Gebken:

Reference is made to the Notices of Pesticide Registration for the subject products, both dated March 16, 2012. These registrations were given one-year time-limited registrations which will expire on March 17, 2013. Since Bayer HealthCare LLC, Animal Health Division, has complied with the conditions of these registrations, we ask that the time limitations for these registrations be removed.

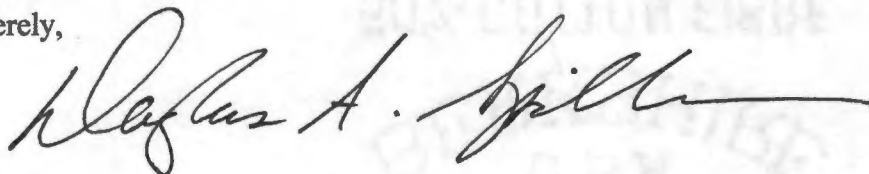
As requested, please find enclosed Pesticide Applications and draft labeling, text dated 02/14/2013, for the subject products (3 copies each) that have been revised pursuant to the guidance given in the respective Notices of Registration, dated 3/16/2012. Due to the nature of some of the requested revisions to the PNR1427 Insecticide label, we have enclosed a red-lined version of this draft label showing the revisions and deletions, in hopes this will allow the Agency to do a more expeditious review of the label.

Therefore with the submission and review of the enclosed labels, we ask the Agency to remove time-limited registration designations for the subject products before the March 17, 2013 expiration date.



If you have any questions, please do not hesitate to call me at 913-268-2751.

Sincerely,

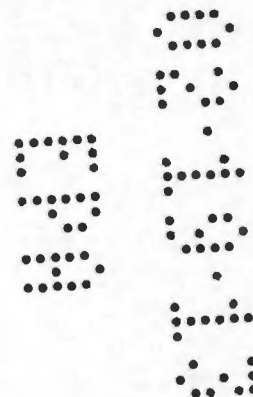


Douglas A. Spilker. Ph. D.
Manager, EPA Regulatory Affairs
Doug.Spilker@Bayer.com

Enclosures:

1. Application for Pesticide Amendment, dated 2/14/2012, for Flumethrin Technical
2. Draft Labeling, text dated, 2/14/2013 for Flumethrin Technical (3 copies)
3. Application for Pesticide Amendment, dated 2/14/2012, for PNR1427 Insecticide, with attachments
4. Draft Labeling, text dated, 2/14/2013 for PNR1427 Insecticide (3 copies)
5. Draft Labeling, text dated, 2/14/2013 for PNR1427 Insecticide (1 copy) – with red-lining

Cc: Ms. B. Alexander (cover letter only via email)



FAST-TRACK AMENDMENTS – Completeness Screening Checklist

Expert's In-Processing Signature: Achaibw Date: 2/25/13 PM #: 10

EPA Reg. Number: <u>11556-154, -155</u>		EPA Receipt Date: <u>2/19/13</u>		
	Checklist Item	Yes	No	N/A
1	Application Form (EPA Form 8570-1) - signed?	✓		
2	Confidential Statement of Formula (EPA Form 8570-29) - signed?			✓
3	Certification with Respect to Citation of Data (EPA Form 8570-34) - signed?			✓
4	Formulator's Exemption Statement (EPA Form 8570-27) - signed?			✓
5	Data Matrix (EPA Form 8570-35) [Applicable for adding me-too uses] - signed?			✓
	a) Selective Method?			
	b) Cite-All Method?			
	c) Public copy of Matrix provided? See PR Notice 98-5			
6	Is Label included? (5 copies)	✓		
	a) Electronic Label submitted?		✓	
Comments: <u>removing time - limited registration restrictions</u>				



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

February 20, 2013

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

DR. BRUCE MARTIN
BAYER HEALTHCARE LLC
ANIMAL HEALTH DIVISION
PO Box 390
SHAWNEE MISSION, KS 66201-0390

PRODUCT NAME: FLUMETHRIN TECHNICAL
COMPANY NAME: BAYER HEALTHCARE LLC
OPP IDENTIFICATION NUMBER:
EPA FILE SYMBOL: 11556-154
EPA RECEIPT DATE: 02/19/13

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Registration Division, Risk Management Team 10, at (703) 305-6701.

Sincerely,

A handwritten signature in black ink, appearing to be "JSA".

Front End Processing Staff
Information Services Branch
Information Technology & Resources Management Division

Fee for Service

{931191E~

This package includes the following

☐ New Registration

☒ Amendment

☐ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: _____

for Division

☐ AD

☐ BPPD

☒ RD

Risk Mgr. **10**

Receipt No.

S-

931191

EPA File Symbol/Reg. No.

11556-154

Pin-Punch Date:

2/19/2013



This item is NOT subject to FFS action.

Action Code:

Requested:

Granted:

Amount Due: \$ _____

Parent/Child Decisions:

☐ Inert Cleared for Intended Use



Uncleared Inert in Product

Reviewer: _____

H. GARVIE

Date: _____

2/20/13

Remarks:

Bayer HealthCare
Animal Health



Via Federal Express

February 14, 2013

Document Processing Desk (AMEND - NO REGFEE)
Office of Pesticide Programs (7504P)
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Room S-4900, One Potomac Yard
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Attention: Mr. Richard Gebken/PM10
Registration Division (7505P)

Subject: **Flumethrin Technical (EPA Reg. No. 11556-154)**
PNR1427 Insecticide (EPA Reg. No. 11556-155); ABN: Seresto
Amendments to remove time-limited registration designations

Bayer HealthCare LLC
Animal Health
P.O. Box 390
Shawnee Mission, KS 66201-0390

Dear Mr. Gebken:

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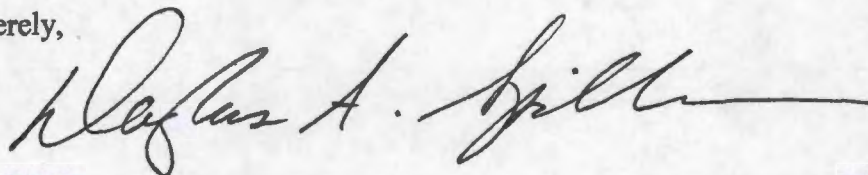
As requested, please find enclosed Pesticide Applications and draft labeling, text dated 02/14/2013, for the subject products (3 copies each) that have been revised pursuant to the guidance given in the respective Notices of Registration, dated 3/16/2012. Due to the nature of some of the requested revisions to the PNR1427 Insecticide label, we have enclosed a red-lined version of this draft label showing the revisions and deletions, in hopes this will allow the Agency to do a more expeditious review of the label.

Therefore with the submission and review of the enclosed labels, we ask the Agency to remove time-limited registration designations for the subject products before the March 17, 2013 expiration date.



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Sincerely,

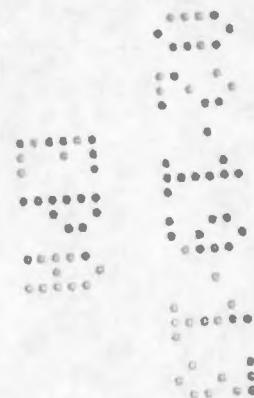


Douglas A. Spilker. Ph. D.
Manager, EPA Regulatory Affairs
Doug.Spilker@Bayer.com

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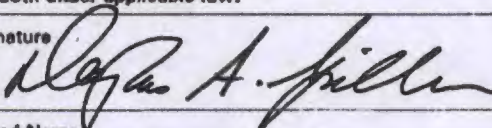
Cc: Ms. B. Alexander (cover letter only via email)





Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060

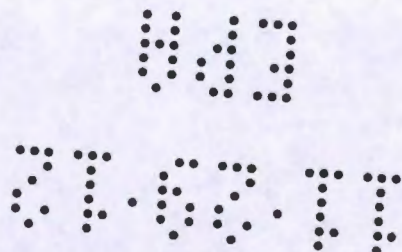
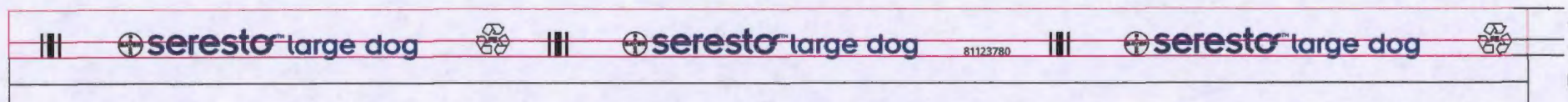
		United States Environmental Protection Agency Washington, DC 20460		<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number
Application for Pesticide - Section I					
1. Company/Product Number 11556-155		2. EPA Product Manager Richard Gebken		3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted	
4. Company/Product (Name) PNR 1427 Insecticide		PM# 10			
5. Name and Address of Applicant (Include ZIP Code) Bayer Healthcare LLC, Animal Health Division P.O. Box 390 Shawnee Mission, KS 66201-0390 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____			
Section - II					
<input type="checkbox"/> Amendment - Explain below.		<input checked="" type="checkbox"/> Final printed labels in response to Agency letter dated <u>March 16, 2012</u>			
<input type="checkbox"/> Resubmission in response to Agency letter dated _____		<input type="checkbox"/> "Me Too" Application.			
<input type="checkbox"/> Notification - Explain below.		<input type="checkbox"/> Other - Explain below.			
Explanation: Use additional page(s) if necessary. (For section I and Section II.) Non-PRIA Action: Submission of Final Printed Labeling for three (3) products with the alternate brand names of the subject registration: Seresto Small Dog, Seresto Large Dog and Seresto Cat (3 copies of each packaging element.) Please note, in addition to full label versions, the submission contains cropped versions of the extended insert labels for better readability. Email Contact: doug.spilker@bayer.com					
Section - III					
1. Material This Product Will Be Packaged In:					
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No * Certification must be submitted	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Unit Packaging wgt. No. per container	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Package wgt. No. per container	2. Type of Container <input checked="" type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 1 collar each (0.44 or 1.6 oz)		5. Location of Label Directions <input type="checkbox"/> _____	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			
Section - IV					
1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Douglas A. Spilker, Ph.D.		Title Manager, EPA Reg. Affairs		Telephone No. (Include Area Code) 913-268-2751	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.				8. Date Application Received (Stamped)	
2. Signature 		3. Title Manager, EPA Reg. Affairs			
4. Typed Name Douglas A. Spilker, Ph.D.		5. Date 28 Nov 2012			

top view
lid



NOT REVIEWED
In Accordance with PR Notice 82-2
Based on Draft Labeling Dated
3-16-12

side view
lid



L&L GmbH & Co. KG L&L Straße 13 40999 Düsseldorf Tel.: 0211 77 46 46-0 • Fax: -410	PM no.: 81123780 CR no.: 011075 Format: 121 mm Font size: 6 pt Drawing no.: 2357	Technology: phone: +49 431 3820... KVP Helke Wulf 128 KVP Holger Schulz 626	
	Colours: CM K Starco	Colourant 01 AG	Text → Presentations: phone: +49 2173 38... Christina Höfer 4724 Rita Felicitas Reich 4098 Yvonne Sabatini 4082 Renate Steinsacker 3046
	Colour inside: Pantone 201	Version no.: 1	
		Date: 15.10.2012	

top view
lid



seresto™ large dog

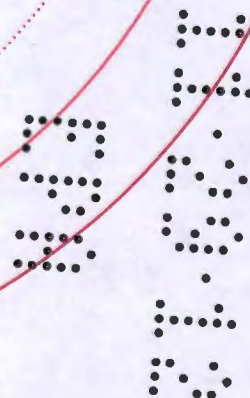
For 8-month prevention and treatment of ticks and fleas on dogs and puppies
7 weeks of age and older and above 18 lbs. (8 kg)
Odorless · 3 Visibility Reflectors Included

Active Ingredients	% by Weight
Flumethrin*	4.5 %
Imidacloprid	10.0 %
Other Ingredients	<u>85.5 %</u>
Total	100.0 %

*Trans Z-1/trans Z-2 ratio:
max 66 % trans Z-1 and min 34 % trans Z-2
Net contents: One collar – 1.6 oz. (45g)

KEEP OUT OF REACH OF CHILDREN

See insert for Directions for Use.





seresto™ large dog

For 8-month prevention and treatment of ticks and fleas
on dogs and puppies 7 weeks of age and older and above 18 lbs. (8 kg)

READ THE ENTIRE LABEL BEFORE USE

DO NOT LET CHILDREN PLAY WITH THIS COLLAR OR REFLECTORS

For CONSUMER QUESTIONS, call 1-800-255-6826.

For medical emergencies involving HUMANS, call 1-800-422-9874.

For medical emergencies involving ANIMALS, call 1-800-422-9874.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Store in original unopened container in a cool, dry place
that is inaccessible to children.

Container Disposal: Dispose of container, pouch and expired collar in trash.

Manufactured for Bayer HealthCare LLC,
Animal Health Division, P.O. Box 390,
Shawnee Mission, KS, 66201, USA

Made in Germany

©2012 Bayer HealthCare LLC

EPA Reg. No. 11556-155, EPA Est. No. 11556-DEU-1

Bayer and the Bayer Cross are registered trademarks of Bayer.

Seresto is a trademark of Bayer.



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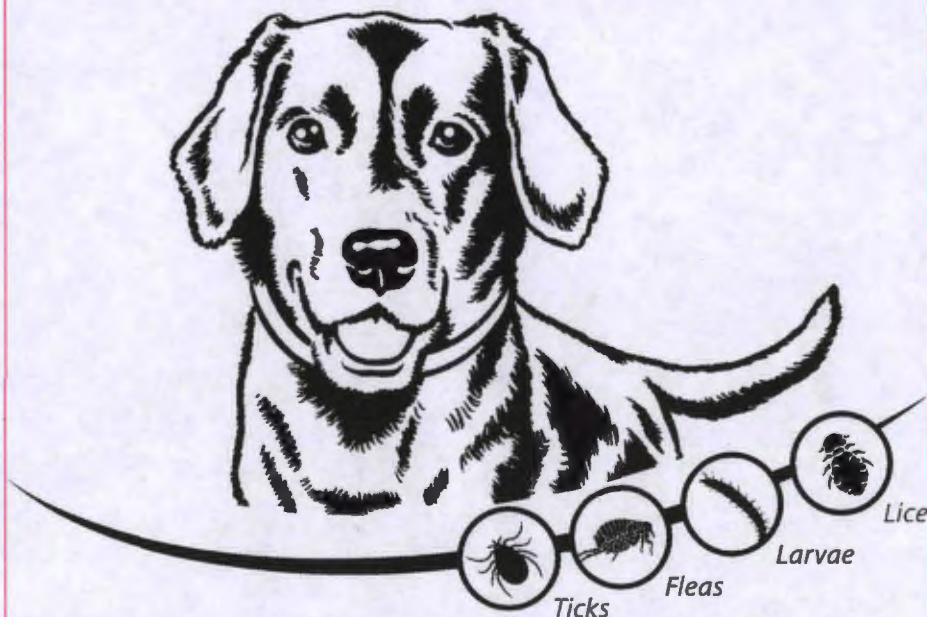
Bayer

81080925

Lot:

21.03.17





seresto™ large dog

4.5 % Flumethrin
10.0 % Imidacloprid

Do not let children play with this collar or reflectors.

FOR USE ON DOGS

See insert for complete label information.

Do not open until ready to use.

81081077

Lot:

Bayer HealthCare LLC,
Animal Health Division
Bayer and the Bayer Cross
are registered trademarks of
Bayer. Seresto is a trademark
of Bayer.

EPA Reg. No. 11556-155
EPA Est. No. 11556-DEU-1

[illegible]



seresto™ large dog

For 8-month prevention and treatment of ticks and fleas on large dogs and puppies 7 weeks of age and older and above 18 lbs. (8 kg)

- Repels and kills ticks for 8 months, including Deer ticks (vector of Lyme disease and anaplasmosis), American dog ticks (vector of Rocky Mountain spotted fever and ehrlichiosis), Brown dog ticks (vector of ehrlichiosis, anaplasmosis, bartonellosis, canine hemoplasmosis, babesiosis, and Rocky Mountain spotted fever), and Lone Star ticks (vector of ehrlichiosis).
- Prevents tick infestations within 48 hours after application.
- Re-infesting ticks are repelled and/or killed as quickly as 6 hours.
- Quickly kills fleas on dogs within 24 hours and continues to prevent infestations for 8 months.
- Treatment with Seresto kills fleas and may reduce the risk of tapeworm infections (*Dipylidium caninum*), bartonellosis (*Bartonella vinsonii*, *Bartonella* spp.), and rickettsiosis (*Rickettsia felis*), which are types of canine vector borne diseases.
- Re-infesting fleas are killed within 2 hours with protection against further flea infestation lasting 8 months.
- Kills fleas before they lay eggs.
- Seresto aids in the control of flea larvae in the dog's surroundings following contact with a Seresto-treated dog.
- Kills chewing lice for one month.
- Aids in the treatment and control of Sarcopic mange.
- No need to remove collar when your pet goes swimming or gets bathed.



This collar is designed with a safety-closure mechanism. In the unlikely event a dog being trapped, the dog's own strength is sufficient to widen the collar to allow for quick release.



Replace the collar after 8 months for optimal tick and flea protection.

PRODUCT INFORMATION

Kills fleas which may cause flea allergy dermatitis (FAD) or flea bite hypersensitivity (FBH).

Seresto kills existing fleas on dogs within 24 hours. Reinfesting fleas are killed within 2 hours with protection against further flea infestation lasting eight (8) months. Pre-existing pupae in the environment may continue to emerge for six (6) weeks or longer depending upon the climatic conditions.

Seresto aids in the control of flea larvae in the dog's surroundings following contact with a Seresto-treated dog.

Ticks already on the dog prior to treatment may not be killed immediately after collar application and may remain attached and visible. At the time of application remove ticks already on the dog. The prevention of infestations with new ticks starts within 48 hours after application of the collar.

Re-infesting ticks are repelled and/or killed as quickly as 6 hours.

Kills lice on dogs for one month.

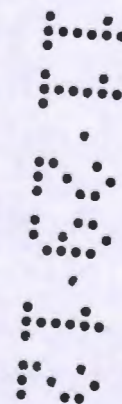
Aids in the treatment and control of Sarcopic mange. Seresto is water-resistant and remains effective following a shampoo treatment, swimming or after exposure to rain or sunlight. Under normal conditions, effectiveness lasts for 8 months. In order to maintain an eight-month duration, dogs must not be bathed more than once per month. For dogs that swim once a month or more, the control duration is reduced to 5 months.

Occasionally slight itching may be observed in animals that are not used to wearing collars in the first few days after fitting. Ensure that the collar is not fitted too tightly. Slight hair loss and mild skin reactions due to the mechanical irritation of the collar may occur at the application site which usually recover within 1 or 2 weeks without the need for collar removal. If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinarian.

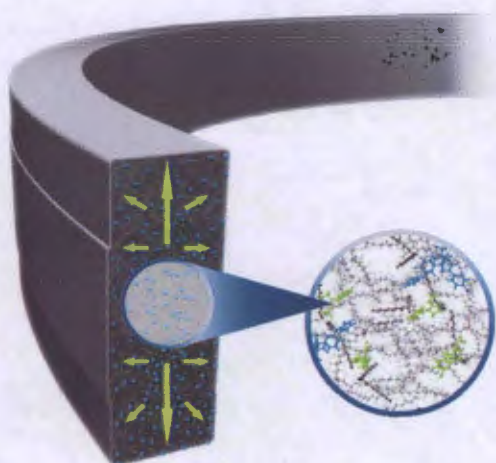
In case of loss of collar, a new collar may be applied immediately.

Do not attach a leash to the collar as this may cause breakage.

Keep the collar in the bag and in the outer packaging until use. As with any pesticide product, do not allow small children to play with the collar or reflectors, or to put them into their mouths. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and cold water after fitting the collar. People with sensitivity reactions to the ingredients of the collar should avoid contact with the collar. Choking hazard. Contains small parts. Do not place collar or reflectors in mouth. Not intended for use on humans.



- Bayer Polymer Matrix ensures that both active ingredients are slowly and continuously released in low concentrations.



- Make sure to replace the collar after 8 months for year-round pest prevention.
- Light reflectors for added visibility in the evening and at night.

Active Ingredients:	% by Weight
Flumethrin*	4.5 %
Imidacloprid	10.0 %
OTHER INGREDIENTS	85.5 %
Total	100 %

* Trans Z-1/trans Z-2 ratio: max 66 % trans Z-1 and min 34 % trans Z-2

READ THE ENTIRE LABEL BEFORE USE

DO NOT OPEN UNTIL READY TO USE

DO NOT LET CHILDREN PLAY WITH THIS COLLAR
OR REFLECTORS

KEEP OUT OF REACH OF CHILDREN
CHOKING HAZARD – CONTAINS
SMALL PARTS

HOT LINE NUMBER

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

- For CONSUMER QUESTIONS, call 1-800-255-6826.
- For medical emergencies involving HUMANS, call 1-800-422-9874.
- For medical emergencies involving ANIMALS, call 1-800-422-9874.



For external use on dogs only. Do not use on other animals. Do not use on puppies under seven weeks of age. Do not get this product in dog's eyes or mouth. As with any product, consult your veterinarian before using this product on debilitated, aged, breeding, pregnant, or nursing animals. Individual sensitivities, while rare, may occur after using ANY pesticide product for pets. If signs of sensitivity occur, remove collar and bathe your pet with mild soap and rinse with large amounts of water. If signs persist, or become more severe, consult a veterinarian immediately. If your animal is on medication, consult your veterinarian before using this or any other product. If your dog is experiencing an adverse event, contact your veterinarian and call 1-800-422-9874.

The Bayer Polymer Matrix System ensures that both active ingredients are slowly and continuously released in low concentrations from the collar towards the animal. This avoids peak concentrations and ensures that concentrations of both active ingredients are present in the dog's haircoat during the entire efficacy period. The active ingredients spread from the site of direct contact over the entire skin surface.



DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not contaminate feed or food.

HOW TO APPLY

One collar per animal to be fastened around the neck. Remove collar from protective bag directly before use. Unroll collar and make sure that there are no remnants from the plastic connectors inside the collar.



Insert end of the collar through the buckle. Adjust the collar around the animal's neck without tightening it too tight (as a guide, it should be possible to insert 2 fingers between the collar and the neck). Pull excess collar through the loop(s) and cut off any excess length extending 1 inch (2 cm) beyond the loop(s).

After application of the collar, three reflector clips may be fixed permanently to the collar to increase the animal's visibility in the dark. Take the clips out of the bag. The clips should be evenly distributed on the non-overlapping part of the collar. The clips are correctly applied when a clicking sound is heard. For safety reasons once the reflectors are fixed to the collar the clasp closes permanently and cannot be re-opened.



The collar should be worn continuously for the 8 month protection period. Check periodically and adjust fit if necessary, especially when puppies are rapidly growing.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Store in original unopened container in a cool, dry place that is inaccessible to children.

Container Disposal: Dispose of container, pouch and expired collar in trash.

LIMITED WARRANTY AND LIMITATION OF DAMAGES
Bayer HealthCare LLC, Animal Health Division, warrants that this material conforms to the chemical description on the label. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY, INCLUDING ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR MERCHANTABILITY, and no agent of Bayer is authorized to do so except in writing with a specific reference to this warranty. To the extent consistent with applicable law any damages arising from a breach of this warranty shall be limited to direct damages and shall not include consequential commercial damages such as loss of profits or values, etc. The reflector clips contained herein are only meant to be used in combination with the specific collar and have been tested only for such use and purpose. To the extent consistent with applicable law, Bayer excludes liability for any misuse and use other than in combination with the specific collar as described in the packaging insert.

EPA Reg. No. 11556-155

EPA Est. No. 11556-DEU-1

Manufactured For
Bayer HealthCare LLC
Animal Health Division
P.O. Box 390

Shawnee Mission, Kansas 66201 USA

Made in Germany

Bayer





United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 11556-155	2. EPA Product Manager Richard Gebken	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) PNR1427 Insecticide	PM# 13	
5. Name and Address of Applicant (Include ZIP Code) Bayer HealthCare LLC, Animal Health Division P.O. Box 390 Shawnee Mission, KS 66201-0390 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input checked="" type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Submission of Final Printed Labeling - No action required. ABNs: Seresto Small Dog; Seresto Large Dog. Attached are labelling proofs for product to be used specifically in the CDC Rocky Mountain Spotted Fever Pilot Prevention program. Commercial packaging for sales launch will submitted later this year.

Contact: doug.spilker@bayer.com

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input checked="" type="checkbox"/> Other (Specify) _____
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt. No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input checked="" type="checkbox"/> Container	4. Size(s) Retail Container 1 Collar	5. Location of Label Directions <input type="checkbox"/> On Label <input checked="" type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)

Name Douglas A. Spilker, Ph D.	Title EPA Reg. Affairs Manager	Telephone No. (Include Area Code) 913-268-2751
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Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature 	3. Title EPA Reg. Affairs Manager	6. Date Application Received (Stamped)
4. Typed Name Douglas A. Spilker, Ph D.	5. Date 30 March 2012	

NOT REVIEWED
In Accordance with PR Notice 82-2
Based on Draft Labeling Dated

Front Panel

Seresto™ Small Dog

For 8-month prevention and treatment of ticks and fleas on small dogs and puppies
7 weeks of age and older and up to 18 lbs. (8 kg)

ACTIVE INGREDIENT:

Flumethrin; [Cyano(4-fluoro-3-phenoxyphenyl)methyl 3-[2-chloro-2-(4-chlorophenyl)ethenyl] -2,2-dimethylcyclopropanecarboxylate]*	4.5%
Imidacloprid.....	10.0%
OTHER INGREDIENTS	85.5%
Total.....	100.0%

*Trans Z-1/trans Z-2 ratio: max 66% trans Z-1 and min 34% trans Z-2

Net Contents: 1 Collar 0.44 oz. (12.5 gm) per collar

EPA Reg. No. 11556-155

EPA Est. No. 11556-KS-1

See insert inside for additional Product Information and Directions for Use.

READ THE ENTIRE LABEL BEFORE EACH USE

**DO NOT OPEN UNTIL READY TO USE
DO NOT LET CHILDREN PLAY WITH THIS COLLAR**

Manufactured For:
Bayer HealthCare LLC, Animal Health Division
P.O. Box 390, Shawnee Mission, Kansas 66201 USA
Made in Germany

Mat. No.: 81544906
Batch No.: KP05KTJ
SSID: 2180

21040

043

Inner Pouch

Seresto™ Small Dog

**10.0% imidacloprid
4.5% flumethrin**

**Do not let children play with this collar
FOR USE ON DOGS**

**See insert for complete label information.
Do not open until ready to use.**

BAYER

**EPA Reg. No. 11556 – 155
EPA Est. No. 11556 – KS – 1**

21.0.40

W3

NOT REVIEWED
In Accordance with PR Notice 82-2
Based on Draft Labeling Dated

Front Panel

Seresto™ Large Dog

For 8-month prevention and treatment of ticks and fleas on large dogs and puppies
7 weeks of age and older and above 18 lbs. (8 kg)

ACTIVE INGREDIENT:

Flumethrin; [Cyano(4-fluoro-3-phenoxyphenyl)methyl 3-[2-chloro-2-(4-chlorophenyl)ethenyl] -2,2-dimethylcyclopropanecarboxylate]*	4.5%
Imidacloprid	10.0%
OTHER INGREDIENTS	85.5%
Total	100.0%

*Trans Z-1/trans Z-2 ratio: max 66% trans Z-1 and min 34% trans Z-2

Net Contents: 1 Collar 1.6 oz. (45.0 gm) per collar

EPA Reg. No. 11556-155

EPA Est. No. 11556-KS-1

See insert inside for additional Product Information and Directions for Use.

READ THE ENTIRE LABEL BEFORE EACH USE

**DO NOT OPEN UNTIL READY TO USE
DO NOT LET CHILDREN PLAY WITH THIS COLLAR**

Manufactured For:
Bayer HealthCare LLC, Animal Health Division
P.O. Box 390, Shawnee Mission, Kansas 66201 USA
Made in Germany

Mat. No.: 81544930
Batch No.: KP05KF6
SSID: 2181

21.00.00

04.03

Inner Pouch

Seresto™ Large Dog

**10.0% imidacloprid
4.5% flumethrin**

**Do not let children play with this collar
FOR USE ON DOGS**

**See insert for complete label information.
Do not open until ready to use.**

BAYER

**EPA Reg. No. 11556 – 155
EPA Est. No. 11556 – KS – 1**

21.00.40

8.43

Seresto™ Small Dog

For 8-month prevention and treatment of ticks and fleas on small dogs and puppies 7 weeks of age and older and up to 18 lbs. (8 kg)

Seresto™ Large Dog

For 8-month prevention and treatment of ticks and fleas on large dogs and puppies 7 weeks of age and older and above 18 lbs. (8 kg)

- Repels and kills ticks for 8 months, including Deer ticks, (*Ixodes scapularis*) vector of Lyme disease and anaplasmosis, American dog ticks, (*Dermacentor variabilis*) vector of Rocky Mountain spotted fever and ehrlichiosis, Brown dog ticks, (*Rhipicephalus sanguineus*) vector of ehrlichiosis, anaplasmosis, bartonellosis, babesiosis, canine hemoplasmosis, and Rocky Mountain spotted fever, and Lone Star ticks (*Amblyomma americanum*) vector of ehrlichiosis
- Prevents tick infestations within 48 hours after application
- Re-infesting ticks are repelled and/or killed as quickly as 6 hours
- Quickly kills fleas on dogs within 24 hours and continues to prevent infestations for 8 months
- Reinfesting fleas are killed within 2 hours with protection against further flea infestation lasting 8 months
- Kills fleas before they lay eggs
- Aids in control of flea larvae in the dog's surrounding
- Treatment with Seresto kills fleas and may reduce the risk of tapeworm infections (*Dipylidium caninum*), Bartonellosis (*Bartonella vinsonii*, *Bartonella* spp.), and Rickettsiosis (*Rickettsia felis*), which are types of canine vector borne diseases
- Aids in the treatment and control of Sarcoptic mange
- Make sure to replace the collar after 8 months for year-round control prevention
- No need to remove collar when your pet goes swimming or gets bathed
- Water resistant
- Patented Bayer polymer matrix ensures that both active ingredients are slowly and continuously released in low concentrations

ACTIVE INGREDIENT:

Flumethrin; [Cyano(4-fluoro-3-phenoxyphenyl)methyl 3-[2-chloro-2-(4-chlorophenyl)ethenyl]-2,2-dimethylcyclopropanecarboxylate]*4.5%
Imidacloprid10.0%

OTHER INGREDIENTS85.5%

Total100.0%

*Trans Z-1/trans Z-2 ratio: max 66% trans Z-1 and min 34% trans Z-2

EPA Reg. No. 11556-155

EPA Est. No. 11556-KS-1

READ THE ENTIRE LABEL BEFORE EACH USE
DO NOT OPEN UNTIL READY TO USE
DO NOT LET CHILDREN PLAY WITH THIS COLLAR
KEEP OUT OF REACH OF CHILDREN

HOT LINE NUMBER

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

- For CONSUMER QUESTIONS, call 1-800-255-6826.
- For medical emergencies involving HUMANS, call 1-800-422-9874.
- For medical emergencies involving ANIMALS, call 1-800-422-9874.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not contaminate feed or food.

HOW TO APPLY

One collar per animal to be fastened around the neck.

Remove collar from protective bag directly before use. Unroll collar and make sure that there are no remnants from the plastic connectors inside the collar. Insert end of the collar through the buckle. Adjust the collar around the animal's neck without tightening it too tight (as a guide, it should be possible to insert 2 fingers between the collar and the neck). Pull excess collar through the loop(s) and cut off any excess length extending beyond 1 inch (2 cm) beyond the loop(s).



The collar should be worn continuously for the 8 month protection period. Check periodically and adjust fit if necessary, especially when puppies are rapidly growing.

This collar is designed with a safety-closure mechanism. In the unlikely event of a dog being trapped, the dog's own strength is sufficient to widen the collar to allow for quick release.

Replace the collar after 8 months for optimal flea and tick protection.

PRODUCT INFORMATION

Kills fleas which may cause flea allergy dermatitis (FAD) or flea bite hypersensitivity (FBH).

Seresto kills existing fleas on dogs within 24 hours. Reinfesting fleas are killed within 2 hours with protection against further flea infestation lasting eight (8) months. Pre-existing pupae in the environment may continue to emerge for six (6) weeks or longer depending upon the climatic conditions. Seresto aids in the control of flea larvae in the dog's surroundings following contact with a Seresto-treated dog.

Ticks already on the dog prior to treatment may not be killed immediately after collar application and may remain attached and visible. At the time of application remove ticks already on the dog. The prevention of infestations with new ticks starts within 48 hours after application of the collar. Re-infesting ticks are repelled and/or killed as quickly as 6 hours.

Aids in the treatment and control of Sarcoptic mange.

Seresto is water resistant and remains effective following a shampoo treatment, swimming or after exposure to rain or sunlight. Under normal conditions, effectiveness lasts for 8 months. In order to maintain an eight-month duration, dogs must not be bathed more than once per month. For dogs that swim once a month or more, the control duration is reduced to 5 months. In case of loss of collar, a new collar may be applied immediately.

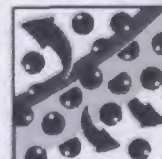
Occasionally slight itching may be observed in animals that are not used to wearing collars in the first few days after fitting. Ensure that the collar is not fitted too tightly. Slight hair loss and mild skin reactions due to the mechanical irritation of the collar may occur at the application site which usually recover within 1 or 2 weeks without the need for collar removal. If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinarian.

Do not attach a leash to the collar as this may cause breakage.

Keep the collar in the bag and in the outer packaging until use. As with any pesticide product, do not allow small children to play with the collar or to put them into their mouths. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and cold water after fitting the collar. People with sensitivity reactions to the ingredients of the collar should avoid contact with the collar. Do not place collar in mouth. Not intended for use on humans.

For external use on dogs only. Do not use on other animals. Do not use on puppies under seven weeks of age. Do not get this product in dog's eyes or mouth. As with any product, consult your veterinarian before using this product on debilitated, aged, breeding, pregnant, or nursing animals. Individual sensitivities, while rare, may occur after using ANY pesticide product for pets. If signs of sensitivity occur remove collar and bathe your pet with mild soap and rinse with large amounts of water. If signs persist, or become more severe, consult a veterinarian immediately. If your animal is on medication, consult your veterinarian before using this or any other product. If your dog is experiencing an adverse event, contact your veterinarian and, call 1-800-422-9874.

The patented Bayer polymer matrix system ensures that both active ingredients are slowly and continuously released in low concentrations from the collar towards the animal. This avoids peak concentrations and ensures that concentrations of both active ingredients are present in the dog's haircoat during the entire efficacy period. The active ingredients spread from the site of direct contact over the entire skin surface.



STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Store in original unopened container in a cool, dry place that is inaccessible to children.

Container Disposal: Dispose of container, pouch and expired collar in trash.

LIMITED WARRANTY AND LIMITATION OF DAMAGES

Bayer HealthCare LLC, Animal Health Division, warrants that this material conforms to the chemical description on the label. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY, INCLUDING ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR MERCHANTABILITY, and no agent of Bayer is authorized to do so except in writing with a specific reference to this warranty. To the extent consistent with applicable law any damages arising from a breach of this warranty shall be limited to direct damages and shall not include consequential commercial damages such as loss of profits or values, etc.

Bayer (reg'd), the Bayer Cross (reg'd), and Seresto are trademarks of Bayer.



Manufactured For
Bayer HealthCare LLC
Animal Health Division
P.O. Box 390
Shawnee Mission, Kansas 66201 USA
Made in Germany

81544906
81544930
16720



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (H7505C)
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

EPA Reg. Number:
11556-155

Date of Issuance:
MAR 16 2012

Term of Issuance:
Unconditional

Name of Pesticide Product:

PNR1427 Insecticide

NOTICE OF PESTICIDE:

☒ Registration
☐ Reregistration

(Under FIFRA as amended)

Name and Address of Registrant (include ZIP Code):

Bayer HealthCare LLC
Animal Health Division
P.O. Box 390
Shawnee Mission, KS 66201-0390

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is **unconditionally** registered in accordance with FIFRA sec. 3(c)(5) for a period of one year from the date of registration. This registration will expire on March 17, 2013.

Once a pesticide is registered, however, it is not regarded as permanently acceptable. Registration does not eliminate the need for continual reassessment of pesticides. If the Agency determines that, at any time, additional data are required to maintain in effect an existing registration, the Agency will require submission of such data under FIFRA section (3).

1. You will make the following label changes before you release the product for shipment:

- a) Revise the EPA Registration Number to read "EPA Reg. No. 11556-155."
- b) Replace the following claim: "For 8-month prevention and treatment of ticks, fleas, and lice on ... etc" with "For 8-month prevention and treatment of ticks and fleas on ... etc". Also replace "Replace the collar after 8 months for (optimal) (continuous) flea, (lice) and tick protection" with "Replace the collar after 8 months for (optimal) (continuous) flea, and tick protection". All claims related to "8 months" must be limited to fleas and ticks only. Other pests are not controlled for that duration.
- c) Claims against lice must be limited to one month.
- d) Tick claims for killing within 6 hours of re-infestation on cats must be removed from the label. Based on the submitted or cited data the claim only is supported for dogs.

Signature of Approving Official:

Richard Gebken
Richard Gebken Product Manager
Insecticide Branch/Registration Division (7505P)

Date:

March 16, 2012

Enclosure